

Remarks

Restriction

The Applicant again requests the Examiner's reconsideration of the restriction requirement. The Applicant disagrees with the restriction between Groups I and II. However, in order to further prosecution, in no way acquiescing to the Examiner's arguments, expressly reserving the right to present the same or similar, the Applicant has presented a new set of claims 18-29.

Since the claimed compounds have a similarity in structure, we do not believe there is an undue search burden. As evidence, we submit a copy of a European Office Action dated 10th October 2005 received for the European patent application equivalent to the present US application. This European Office Action contains the results of a search which was restricted to a generic group defined by compounds wherein:

R^2 is optionally substituted phenyl,

M is $-(CH_2)_{0-2}-O-$ and

A is one of the options (i) to (iv) in [original] claim 1.

The European Office Action is contained in the IDS submitted herewith.

With regard to the pending independent Claim 18, the Applicant has limited formula I such that M is $-(CH_2)-O-$, and R^2 is optionally-substituted phenyl, and A is selected from a direct bond, optionally substituted C_{1-3} alkylene, carbonyl or $-C(O)-C(R^dR^d)-$, wherein R^d is independently selected from a direct bond hydrogen and C_{1-2} alkyl.

No new matter has been added and basis for the embodiments are as follows:

R^2 is optionally substituted phenyl [Basis: Page 18, line 11];

M is $-(CH_2)-O-$ [Basis: Page 28, line 26]; and

A is selected from a direct bond, optionally substituted C_{1-3} alkylene, carbonyl or

$-C(O)-C(R^dR^d)-$, wherein R^d is independently selected from a direct bond hydrogen and C_{1-2} alkyl. [Basis: Page 27, lines 12-14].

R^6 and R^{6a} limitations can be found on page 21, lines 10 to 12; and

B limitation can be found on Page 27, lines 17-21.

The Applicant believes these claims contain unity of invention. Unity of invention exists with regard to the original and pending claims. “Whether or not any particular technical feature makes a ‘contribution’ over the prior art, and therefore constitutes a ‘special technical feature,’ should be considered with respect to novelty and inventive step.” 37 CFR 1.475 Unity of Invention Before the International Searching Authority, the International Preliminary Examining Authority and **During the National Stage.**” (emphasis added). However, “[w]hen the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: (A) All alternatives have a common property or activity; and (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives.” MPEP 1850 III.B. Markush Practice.

Unity of invention exists for the original and pending claims because, as a group, the compounds make a contribution over the prior art, i.e., the compounds have common structural attributes and have gonadotropin releasing hormone (GnRH) activity.

The Examiner argues that Cai et al., (U.S. Patent No . 6936603) and Dickinson et al., (U.S. Patent No . 3277100) cause the claims to lack unity. We disagree. The original and pending claims are novel and non-obvious in light of Cai and Dickinson. Neither Cai nor Dickinson provide compounds with gonadotropin releasing hormone (GnRH) activity. The Examiner has cited no law, rule, or regulation suggesting that the mere existence of some overlapping disclosure is sufficient for anticipation. Anticipation requires that the reference disclose the claimed invention and all its elements. The courts have long held that mere overlapping generic disclosure is not anticipatory. In re Petering, the court held

The compounds encompassed by these claims, reciting as all of them do an ethyl group, C(2)H(5), at the 6-position or ethyl groups at the 6- and 7-positions, are not included in the limited class which we find in Karrer. Therefore, it is our opinion that these compounds have not been described by Karrer within the meaning of 35 U.S.C. 102(b) 301 F.2d 676 (1962)

Anticipation of a generic claim may be provided by the disclosure of a species of the genus within the reference. The Examiner has pointed to no such species. “A

'generic claim cannot be allowed to an Applicant if the prior art discloses a species falling within the claimed genus.' The species in that case will anticipate the genus." MPEP 2131.02 Genus-species situations, citing *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960). Cai and Dickinson provide no such compound.

Finally, we resubmit to the Examiner that any restriction requirement that forces one to amend a description of a claim is improper, as it is in fact a rejection in the form of a refusal to examine what the Applicant believes to be the invention. We request reconsideration. The statements in 37 CFR 1.475(c) and PCT rule 13.3 are invalid as in violation of 35 USC Section 112, second paragraph because that Applicant is allowed to distinctly claim the subject matter the applicant regards as his invention. Please consider the arguments provided by Justice Rich in the Concurring Opinion of *In re Weber* with regard to 35 USC Section 121 applicable hereto:

"[I]nventions are claimed," has connoted separate claims to separate inventions. It has no reference to generic or broad claims which "embrace" (the term used by the examiner and the board herein) or "cover" (the term used in the solicitor's brief in support of the board) two or more inventions. *Section 121* nowhere uses the words "embraced" or "covered." It says "claimed," and that I take to mean what it has always referred to in the terminology of the patent law, a "claim" or definitional paragraph which, in the words of *§ 112*, second paragraph, is "particularly pointing out and distinctly claiming the subject matter the applicant regards as his invention." . . .

The fault in the PTO position is that it overlooks the obvious fact that almost any reasonably broad claim "embraces" or "covers" a multiplicity of inventions, in the sense of "dominating" them, which inventions might be separately patentable if and when presented in separate applications. Logically, this is not a sufficient excuse for refusing to examine a claim on its merits for compliance with *35 USC 101, 102, 103, and 112*. None of those statutory sections, of course, justifies a refusal to examine. 580 F.2d 455, 1978.

Section 112

The Examiner has rejected Claims as not satisfying 35 USC Section 112 for reciting, "prodrugs" and "solvates." We disagree. However, in order to further prosecution, in no way acquiescing to the Examiner's argument, expressly reserving the

right to prosecute the same or similar claim, the Applicant has submitted the term “in-vivo hydrolyzable ester” and deleted the terms “prodrugs ” and “solvate.”

The Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. 100811-1P US.

Respectfully submitted,

/James C. Mason /

Name: James C. Mason
Dated: July 29, 2008
Reg. No.: 50,255
Phone No.: 781-839-4016
Global Intellectual Property, Patents,
AstraZeneca R&D Boston,
35, Gatchouse Drive,
Waltham, MA 02451